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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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DR. MILTON HODOSH

Plaintiff,

Case No. 07cv7809 (VM) (DFE)

- against -

MILESTONE SCIENTIFIC INC.

Defendant.

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ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant in the above-captioned action, Milestone Scientific Inc. ("Milestone" or "Defendant"), by and through its attorneys Brown Rudnick Berlack Israels LLP, as and for its answer to the complaint (the "Complaint") of Dr. Milton Hodosh ("Hodosh" or "Plaintiff"), dated September 4, 2007, respectfully alleges as follows:

GENERAL DENIAL

Milestone denies each and every allegation in the Complaint unless it is specifically admitted or otherwise pled.

PARTIES

1. Milestone admits the allegations contained in paragraph 1 of the Complaint.
2. Milestone admits the allegations contained in paragraph 2 of the Complaint.

JURISDICTION AND VENUE

3. Milestone admits the allegations contained in paragraph 3 of the Complaint, except denies that Hodosh has valid causes of action under the sections of Title 28 of the United States Code referenced therein.

4. Paragraph 4 of the Complaint contains legal conclusions to which no response is required. To the extent any response is required, Milestone denies the allegations contained therein, and respectfully refers this Court to the sections of Title 28 of the United States Code referenced therein for their full meaning and import.

PERSONAL JURISDICTION

5. Paragraph 5 of the Complaint contains legal conclusions to which no response is required. To the extent any response is required, Milestone denies the allegations contained therein, and respectfully refers this Court to the sections of the New York Civil Practice Law and Rules referenced therein for its full meaning and import.

6. Paragraph 6 of the Complaint contains legal conclusions to which no response is required. To the extent any response is required, Milestone denies that it is subject to jurisdiction based on section 302(a)(2) of the CPLR, but admits that Milestone transacts certain business in the State of New York and contracts to supply certain goods in the State of New York.

7. Milestone denies the allegations contained in paragraph 7 of the Complaint, except admits that Milestone transacts certain business in the State of New York and contracts to supply certain goods in the State of New York.

8. Milestone denies the allegations contained in paragraph 8 of the Complaint.

9. Milestone denies the allegations contained in paragraph 9 of the Complaint.

GENERAL ALLEGATIONS

10. Milestone denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint, and therefore denies the same.

11. Milestone denies knowledge or information sufficient to form a belief as to the true of the allegations contained in paragraph 11 of the Complaint, and therefore denies the same.

12. Milestone denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint, and therefore denies the same.

13. Milestone denies the allegations contained in paragraph 13 of the Complaint, except avers that certain of Milestone products are sold in certain jurisdictions in the United States.

14. Milestone denies each and every allegation contained in paragraph 14 of the Complaint, except admits that Hodosh had notified Milestone that its actions amounted to an alleged infringement of the '161 Patent.

15. Milestone denies the allegations contained in paragraph 15 of the Complaint.

16. Milestone denies the allegations contained in paragraph 16 of the Complaint.

17. Milestone denies the allegations contained in paragraph 17 of the Complaint.

FIRST CLAIM FOR RELIEF

**PATENT INFRINGEMENT IN
VIOLATION OF 35 U.S.C. § 271**

18. Milestone repeats and realleges each and everyone one of its responses to the allegations contained in paragraphs 1 through 17 of the Complaint with the same force and effect as if fully set forth herein.

19. Paragraph 19 of the Complaint contains legal conclusions to which no response is required. To the extent any response is required, Milestone denies the allegations contained therein and respectfully refers this Court to the section of Title 35 of the United States Code referenced therein for its full meaning and import.

AFFIRMATIVE DEFENSES

AS AND FOR A FIRST AFFIRMATIVE DEFENSE

20. Hodosh fails to state a claim upon which relief can be granted.

AS AND FOR A SECOND AFFIRMATIVE DEFENSE

21. Hodosh's claims in this Court, in whole or in part, are barred by another action pending between the same parties for the same cause of action in the United States District Court for the District of New Jersey.

AS AND FOR A THIRD AFFIRMATIVE DEFENSE

22. Hodosh's claims are not sufficiently plead under the applicable law(s).

AS AND FOR A FOURTH AFFIRMATIVE DEFENSE

23. The products and/or methods manufactured, used, imported, marketed, sold, offered for sale or licensed by Milestone involve apparatus and/or methods that are not infringing within the meaning of Title 35 of the United States Code, § 271 in that there is no literal

infringement of all elements of Hodosh's patent claims, and Milestone has not directly infringed, contributorily infringed, or induced others to infringe, any claim of the '161 Patent.

AS AND FOR A FIFTH AFFIRMATIVE DEFENSE

24. The products and/or methods manufactured, used, imported, marketed, sold, offered for sale or licensed by Milestone involve apparatus and/or methods that are not infringing within the meaning of Title 35 of the United States Code, § 271 because there is no infringement under the doctrine of equivalents.

AS AND FOR A SIXTH AFFIRMATIVE DEFENSE

25. On information and belief, the '161 Patent is invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, §§ 101, 102, 103 and/or 112 and general principles of patent law, and more specifically:

(a) The '161 Patent does not particularly point out and distinctly claim any novel or non-obvious combination which Hodosh claims as its invention, as required by Title 35, United States Code;

(b) In light of the prior art at the time the alleged invention was made, the subject matter as claimed in the '161 Patent would have been obvious to one skilled in the art to which the alleged invention relates and does not constitute any patentable invention; and

(c) Hodosh did not invent the subject matter patented, nor did it make any invention or discovery, either novel, original or otherwise within the meaning of the United States Code, Title 35.

AS AND FOR A SEVENTH AFFIRMATIVE DEFENSE

26. Hodosh has not been damaged in any amount or manner by reason of any act alleged against Milestone in the Complaint, or at all, and therefore, the relief prayed for in the Complaint cannot be granted.

AS AND FOR A EIGHTH AFFIRMATIVE DEFENSE

27. The Complaint was brought in bad faith by Hodosh to damage the relationship between Milestone and its customers to unfairly compete with Milestone.

AS AND FOR AN NINTH AFFIRMATIVE DEFENSE

28. The ‘161 Patent, in order to be deemed valid, is so restricted in scope that Milestone has not infringed any such claims.

AS AND FOR A TENTH AFFIRMATIVE DEFENSE

29. Hodosh is estopped from construing any claim that the ‘161 Patent is infringed or has been infringed, either literally or by application of the doctrine of equivalents, by any products and/or methods manufactured, used, imported, marketed, sold, offered for sale or licensed Milestone because of limitations in the claims of the ‘161 Patent.

AS AND FOR A ELEVENTH AFFIRMATIVE DEFENSE

30. Upon information and belief, Hodosh’s claims are barred by the doctrines of laches, waiver and/or estoppel because Hodosh has unreasonably delayed in asserting his purported rights under the ‘161 Patent to the prejudice of Milestone.

AS AND FOR A TWELFTH AFFIRMATIVE DEFENSE

31. Upon information and believe, the ‘161 Patent is unenforceable because Hodosh is guilty of patent misuse in that Hodosh has sought to impermissibly broaden the physical scope of the grant of the ‘161 Patent with anticompetitive effect.

AS AND FOR A THIRTEENTH AFFIRMATIVE DEFENSE

32. Milestone reserves its right to assert additional affirmative defenses which may become apparent during discovery in this action.

COUNTERCLAIMS

Defendant, Milestone Scientific Inc. ("Milestone" or "Counterclaim Plaintiff"), by and through its undersigned counsel, hereby counterclaims against plaintiff, Dr. Milton Hodosh ("Hodosh" or "Counterclaim Defendant"), and in support thereof, alleges as follows:

NATURE OF THE DISPUTE

1. The following counterclaims arise under the patent laws of the United States, in particular, 35 U.S.C. § 271, and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

2. The counterclaims seek to obtain a declaration, pursuant to 28 U.S.C. §§ 2201 and 2202, that (i) Milestone has not, at any relevant time, infringed U.S. Patent No. 6,159,161 entitled "Microprocessor-Controlled Fluid Dispensing Apparatus" (the "'161 Patent") as to which Hodosh claims to be the exclusive owner, and (ii) pursuant to 35 U.S.C. §§ 101, 102, 103 and/or 112, the '161 Patent is invalid. A copy of the '161 patent is attached hereto as Exhibit A.

3. Milestone's claim for a declaration arises from Hodosh's filing of this action, which adversely effects Milestone's ongoing production, manufacturing, marketing and selling of its fluid delivery systems, including the STA Single Tooth Anesthesia System™ (the "STA System") and the CompuDent Computer Controlled Anesthetic Delivery System™ (the "CompuDent System"). As a result, Milestone hereby seeks from this Court a declaration that

(i) the '161 Patent is invalid and (ii) Milestone's products, including the STA System and CompuDent System, do not infringe the '161 Patent.

THE PARTIES

4. Plaintiff Milestone is a Delaware Corporation with its principal place of business at 220 South Orange Avenue, Livingston, New Jersey 07039. Milestone develops, manufactures, markets and sells dental equipment and related disposable and consumable items and other products for use primarily by dentists, physicians and hospitals.

5. Upon information and belief, defendant Dr. Milton Hodosh is an individual residing at 243 Elmwood Avenue, Providence, Rhode Island 02906. Hodosh claims to be the exclusive owner of the '161 Patent.

JURISDICTION AND VENUE

6. This Court has personal jurisdiction over Hodosh because, *inter alia*, Hodosh has submitted to its jurisdiction by filing the complaint in this action ("Complaint").

7. This Court has subject matter jurisdiction over all claims at issue in this action pursuant to 28 U.S.C. §§ 1331, 1338(a) in that the matter in controversy arises under an Act of Congress relating to patents, plant variety protection, copyrights and trademarks, and pursuant to 28 U.S.C. § 2201(a) and 2202.

8. Hodosh has selected this venue by filing the Complaint with this Court.

FACTS RELEVANT TO ALL COUNTS

The Different Functions Of The STA System, The CompuDent System And The '161 Patent

9. The STA System and CompuDent System are computer-controlled local anesthetic injection delivery systems used by dentists and physicians for delivering anesthetic to tissue.

10. Upon information and belief, the object of the invention of the '161 Patent is to inject the anesthetic at a pressure which is not greater than the normal pressure of tissue to avoid pain caused by injections by the over-distention of tissue. The '161 Patent performs such function by aiding the professional in determining a tissue injection pressure for a certain injection site. The '161 Patent states that the tissue injection pressure is determined by injecting a small amount of anesthetic into the injection site for a few seconds, stopping the injection and then measuring the normal pressure of the tissue by a pressure transducer. The pressure transducer sends this measurement of the tissue's normal pressure to a microprocessor, which, in turn, instructs a motor to operate at a speed which will deliver the anesthetic at a pressure no greater than the natural pressure of tissue. This method prevents delivery of the anesthetic to the injection site at a pressure which will cause the tissue to over-distend, causing pain to the patient.

11. The '161 patent includes method claims 1-5 and 10, and apparatus claims 6-9 and 11-15.

12. Claims 1-5 and 10 of the '161 patent claim a method for injecting fluid into tissue which includes the steps of "determining a tissue injection pressure for an injection site of" tissue and "injecting said fluid into said injection site at a pressure which is not greater than said tissue injection pressure".

13. Neither the STA System nor the CompuDent System measure the normal pressure of tissue. Nor do they determine a tissue injection pressure by stopping the injection at a site.

14. The '161 patent states that the housing of its fluid dispensing apparatus houses, *inter alia*, the power supply, motor and drive mechanism, and that this housing is held in one hand like a pen during operation. Claim 6 of the '161 patent recites "a fluid dispensing

apparatus for dispensing fluid from a carpule having an axially slidable piston" which comprises, among other things, "a hollow housing having an elongate chamber formed therein, said housing extending generally along an axis and being constructed and arranged to be gripped within a person's hand".

15. The housing of the STA System and the CompuDent System, which contain a motor and drive mechanisms, are not "constructed and arranged to be gripped within a person's hand", as required by claim 6 and of the '161 patent. In contrast, the housing for these systems stand on a flat surface during operation.

16. The STA System and CompuDent System do not include, *inter alia*, "a microprocessor capable of driving said motor at a number of speeds, each of said number of speeds corresponding to a specific pressure at which said fluid is dispensed from said carpule", as required by claims 7, 8, 9 and 11-17.

Plaintiff's Apprehension Of An Action To Enforce The '161 Patent

17. Despite the obvious differences between the STA System, the CompuDent System and the claims of the '161 Patent, defendant Hodosh has repeatedly asserted that the STA System and the CompuDent System infringe the '161 Patent. True and accurate copies of demand letters from Hodosh to Milestone are annexed hereto and made a part thereof as Exhibit B.

18. In addition, Hodosh has commenced a real and immediate suit for infringement of the '161 Patent. The Court is respectfully referred to the Complaint herein, dated September 4, 2007, for its contents.

The Present Activity Which Could Be Alleged To Constitute Infringement

19. Milestone presently develops, manufactures, markets and sells its products, including the STA System and the CompuDent System in the United States, in the medical and dental fields, which are alleged to constitute activity that infringes the '161 Patent.

20. Based upon the totality of the circumstances, including, but not limited to, Hodosh's commencement of this action and Milestone's presently existing activity which is alleged to constitute infringement, it is clear that a justiciable and actual controversy exists between Milestone and Hodosh as to the infringement of the '161 Patent.

The Invalidity of the '161 Patent

21. Upon information and belief, prior art that discloses the claim limitations and features of the '161 Patent exist making the claims invalid and unenforceable.

22. The prior art, like the claims of the '161 Patent, disclose methods of injecting fluid into a patient that reduces pain. Requirements of the claims of the '161 Patent, such as determining a tissue injecting pressure, injecting a patient at a constant injection delivery pressure, and injecting fluid into an injection point at a pressure that is not greater than the measured tissue injection pressure, are also disclosed in the prior art.

23. The prior art has also uncovered similar apparatuses, such as those claimed in the '161 Patent, including hypodermic injection devices that include, among other things, a vial of fluid (anesthetic), a multi-speed motor used to dispense fluid from the vial at a constant discharge pressure and microprocessor circuitry for controlling the same.

24. Because the '161 Patent and its claim limitations and features are anticipated by prior art, the invention lacks novelty.

25. Further, in light of the prior art, the differences between the '161 Patent and the prior art are such that the subject matter to be patented (the '161 Patent) as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains at the time the invention was made.

26. Therefore, based upon the fact that the '161 Patent lacks novelty and is obvious in view of prior art, the '161 Patent is invalid.

COUNT I

(Declaratory Judgment of Non-Infringement of the '161 Patent by the STA System)

27. Milestone repeats and realleges the allegations of paragraphs 1 through 26 as if set forth herein.

28. Milestone's fluid delivery systems, including the STA System, do not infringe directly or contribute to the infringement of the '161 Patent.

29. Milestone does not contributorily infringe or induce others to infringe the '161 Patent because the use of its products, including the STA System, will not fall within the scope of any claim of the '161 Patent, and therefore does not infringe any such claim.

30. Hodosh's assertions of infringement irreparably injure Milestone and adversely affect Milestone's business.

31. Unless Hodosh is enjoined therefrom, Hodosh will continue to assert that Milestone and/or its customers are infringing the '161 patent by making, offering for sale, selling or using its fluid delivery systems, including the STA System, and Hodosh will continue to interfere, or threaten to interfere with Milestone's business with respect thereto.

32. To resolve the legal and factual questions raised by Hodosh, and to afford relief from the uncertainty and controversy which Hodosh's assertions and demands have precipitated,

Milestone is entitled to have the question of the infringement of the '161 patent resolved promptly so that Milestone may conduct its business affairs in accordance with the Court's determination of its rights.

33. Milestone has no adequate remedy at law.

34. Milestone is entitled to a declaratory judgment that its fluid delivery systems, including the STA System, do not infringe on any claim of the '161 Patent.

COUNT II

(Declaratory Judgment of Non-Infringement of the '161 Patent by the CompuDent System)

35. Milestone repeats and realleges the allegations of paragraphs 1 through 34 as if set forth herein.

36. Milestone's fluid delivery systems, including the CompuDent System, do not infringe or contribute to the infringement of the '161 Patent.

37. Milestone does not contributorily infringe or induce others to infringe the '161 Patent because the use of its products, including the CompuDent System, will not fall within the scope of any claim of the '161 Patent, and therefore does not infringe any such claim.

38. Hodosh's assertions of infringement irreparably injure Milestone and adversely affect Milestone's business.

39. Unless Hodosh is enjoined therefrom, Hodosh will continue to assert that Milestone and/or its customers are infringing the '161 patent by making, offering for sale, selling or using its fluid delivery systems, including the CompuDent System, and Hodosh will continue to interfere, or threaten to interfere with Milestone's business with respect thereto.

40. To resolve the legal and factual questions raised by Hodosh, and to afford relief from the uncertainty and controversy which Hodosh's assertions and demands have

precipitated, Milestone is entitled to have the question of the infringement of the '161 patent resolved promptly so that Milestone may conduct its business affairs in accordance with the Court's determination of its rights.

41. Milestone has no adequate remedy at law.

42. Milestone is entitled to a declaratory judgment that its fluid delivery systems, including the CompuDent System, do not infringe on any claim of the '161 Patent.

COUNT III

(Declaratory Judgment of Patent Invalidity of the '161 Patent)

43. Milestone repeats and realleges the allegations of paragraphs 1 through 42 as if set forth herein.

44. Claims of the '161 Patent are invalid under one or more of the provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

45. Milestone is entitled to a declaratory judgment that the claims of the '161 Patent are invalid.

WHEREFORE, for the foregoing reasons, Milestone respectfully requests that this Court:

- (i) dismiss the Plaintiff's Complaint, with prejudice;
- (ii) issue a declaration that Milestone has not infringed, induced others to infringe, or contributed to any infringement of, any of the claims of the 161' Patent;
- (iii) issue a declaration that it is the right of Milestone to continue making, using, offering for sale and selling its fluid delivery systems, including its STA System and CompuDent System, without any threat or other

- interference whatsoever against Milestone or Milestone's customers by Hodosh, based on or arising out of the ownership of the '161 Patent;
- (iv) issue a declaration that the '161 Patent is invalid, unenforceable, and not infringed by Milestone;
 - (v) issue a declaration that this case is exceptional under 35 U.S.C. §285;
 - (vi) award Milestone the costs and expenses incurred in connection with this proceeding, including reasonable attorneys', accountants' and experts' fees and costs; and
 - (vii) award Milestone such other and further relief as this Court may deem just and proper.

Dated: New York, New York
November 5, 2007

BROWN RUDNICK BERLACK ISRAELS LLP

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